

ANTACID - aluminum hydroxide, magnesium hydroxide, simethicone liquid

Rugby Laboratories

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Rugby Regular Strength Antacid Liquid

ACTIVE INGREDIENTS (in each 5 mL)

Aluminum hydroxide (equiv. to dried gel, USP) 200 mg

Magnesium hydroxide 200 mg

Simethicone 20 mg

PURPOSE

Antacid

Antacid

Antigas

USE(S)

relieves:

- acid indigestion
- heartburn
- sour stomach
- upset stomach and gas associated with these symptoms

WARNINGS

Do not take more than 80 mL in a 24-hour period, or use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a doctor.

ASK A DOCTOR BEFORE USE IF YOU HAVE

- kidney disease
- a magnesium-restricted diet

ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE

- presently taking a prescription drug. Antacids may interact with certain prescription drugs.

STOP USE AND ASK DOCTOR

if symptoms last more than two weeks

KEEP OUT OF REACH OF CHILDREN

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DIRECTIONS

- **shake well before use**
- mL = milliliter
- adults and children 12 years and older: take 10 mL to 20 mL two times a day, or as directed by a doctor
- children under 12 years: consult a doctor

OTHER INFORMATION

- **each 5 mL contains:** magnesium 85 mg, sodium 5 mg
- store at controlled room temperature 20°C-25°C (68°-77°F)
- do not freeze

INACTIVE INGREDIENTS

ethyl alcohol, flavor, glycerin, hydroxyethyl cellulose, methylparaben, propylene glycol, propylparaben, purified water, saccharin sodium, simethicone emulsion, sorbitol

PRINCIPAL DISPLAY PANEL

Rugby

NDC 0536-1293-83

Regular Strength

Antacid Liquid

Aluminum hydroxide

Magnesium hydroxide

Simethicone

200 mg/200 mg/ 20 mg

Antacid and Antigas

Original Flavor

Relief of:

Heartburn

Acid Indigestion

Sour Stomach

Pressure & Bloating

12 FL OZ (355 mL)

Alcohol content 0.2% v/v



NDC 0536-1293-83

Regular Strength

Antacid Liquid

Aluminum Hydroxide
Magnesium Hydroxide
Simethicone

200 mg/200 mg/20 mg

Antacid and Antigas
Original Flavor

Relief of:

Heartburn
Acid Indigestion
Sour Stomach
Pressure and Bloating

12 FL OZ (355 mL)

Alcohol Content 0.2% v/v

Drug Facts**DO NOT USE IF PRINTED SEAL
UNDER CAP IS BROKEN OR MISSING****Active ingredients (in each 5 mL)****Purpose**

Aluminum hydroxide (equiv. to dried gel, USP) 200 mg.....Antacid
Magnesium hydroxide 200 mg.....Antacid
Simethicone 20 mg.....Antigas

Uses relieves: ■ acid indigestion ■ heartburn ■ sour stomach
■ upset stomach and gas associated with these symptoms

Warnings

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Ask a doctor before use if you have ■ kidney disease
■ a magnesium-restricted diet

Ask a doctor or pharmacist before use if you are ■ presently taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if symptoms last more than two weeks

Keep out of reach of children.

Directions

■ shake well before use ■ mL = milliliter
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Other information

■ each 5 mL contains: magnesium 85 mg, sodium 5 mg ■ store at controlled room temperature 20°C-25°C (68°F-77°F) ■ do not freeze

Inactive ingredients

ethyl alcohol, flavor, glycerin, hydroxyethyl cellulose, methylparaben, propylene glycol, propylparaben, purified water, saccharin sodium, simethicone emulsion, sorbitol.

Distributed by: **RUGBY* LABORATORIES**
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Questions or comments?
Call 1-800-645-2158
www.rugbylaboratories.com

Rev. 05/20 R-30 Re-order No. 371027 MFR# 53041



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ANTACID

aluminum hydroxide, magnesium hydroxide, simethicone liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1293
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE	200 mg in 5 mL
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM HYDRO XIDE	200 mg in 5 mL

DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)			DIMETHICONE	20 mg in 5 mL
Inactive Ingredients				
Ingredient Name				Strength
ALCOHOL (UNII: 3K9958V90M)				
GLYCERIN (UNII: PDC6A3C0OX)				
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SORBITOL (UNII: 506T60A25R)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
Product Characteristics				
Color		WHITE	Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1293-83	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL		part331	07/09/2020	

Labeler - Rugby Laboratories (079246066)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(0536-1293)

Revised: 9/2019

Rugby Laboratories